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09/715,853	11/17/2000	Ashvin H. Desai	010284-0269451	8968

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EXAMINER	
RAGONESE, ANDREA M	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/715,853	DESAI, ASHVIN H.	
	Examiner	Art Unit	
	Andrea M. Ragonese	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,15,17,20,21,24,25,30,33 and 37-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,15,17,20,21,24,25,30,33 and 37-43* is/are rejected.

7)☒ Claim(s) *10,15,17,20,21,24,25,30,33 and 37-43* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed on December 9, 2005 has been entered. Examiner acknowledges that the specification and **claims 10, 15, 17, 21, 24, 30, 33, 37, 41** and **43** have been amended, and **claim 1** has been canceled. Subsequently, **claims 10, 15, 17, 20, 21, 24, 25, 30, 33** and **37-43** are under consideration.

2. The replacement drawing sheets were received on December 9, 2005. These drawings are acceptable.

3. The Examiner acknowledges that Applicant made a bona fide attempt to address the rejections made under 35 U.S.C. 101, however, the rejection is reiterated hereinafter since Applicant was unsuccessful in overcoming the rejection. The Examiner recommends amending the claims in order to remove any references to "**said** body tissue" or "**said** volume" since these phrases refer to parts of a human body. It is suggested that Applicant utilizes the phrases —**the** body tissue— and —**the** volume— instead.

Response to Arguments

4. Applicant's arguments filed December 9, 2005 have been fully considered but they are not persuasive.

On page 15, Applicant states, "Edwards does not describe a biodegradable microsphere container." However, the Examiner strongly disagrees. The microspheres of Edwards "are tiny hollow metallic spheres...[with] a thin coating **104** [that] is provided around the entire surface of each of the microspheres **101**" (see column 16, lines 35-

41). Edwards further discloses, "the coating **104** could simply be biodegradable for chemical stripping by the body's natural fluids...[for] site specific application of the therapeutic drug within the neoplasm...as well as an accurately controlled time release of the drugs into the neoplasm" (see column 16, lines 47-52).

In addition, Applicant states, "Edwards teaches away from biodegradable microspheres." Again, the Examiner strongly disagrees. Not only does Edwards provide adequate disclosure, but also motivation to use such a type of material to produce microspheres, at least in part. Applicant has not claimed that the microspheres of the instant application are "entirely" or "completely" biodegradable, and thus, as broadly and reasonably interpreted by the Examiner, the microspheres of the prior art meet the claim limitations of "biodegradable microsphere containers."

Applicant is reminded that in order to amend the claims to overcome the prior art of record, there must be sufficient support in the original specification for any amendments made to the claims. The Examiner does not believe the specification of the instant invention, as originally filed, supports any type of microsphere that is entirely or completely biodegradable.

Specification

5. The disclosure is objected to because of the following informalities: on page 13, line 8, "Prostatic Hyperplenia" should be deleted and —prostatic hyperplasia— should be inserted therefor.

Appropriate correction is required.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. **Claims 10, 15, 17, 20, 21, 24, 25, 30, 33** and **37-43** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,231,591 B1 in view of Unger et al. (US 5,542,935). Although the conflicting claims are not identical, the claims of the current application are broader in some respects and more specific in others. The claims of U.S. Patent No. 6,231,591 B1 do not recite a treatment that is a microsphere. However, Unger et al. teaches a method of therapeutic drug delivery via microspheres, as stated in the Abstract. Therefore, it would have been obvious to incorporate, through the use of the method as disclosed in U.S. Patent No. 6,231,591 B1, the delivery of microspheres, as taught by Unger et al., for the purpose of timed/controlled release of a therapeutic drug.

8. **Claims 10, 15, 17, 20, 21, 24, 25, 30, 33** and **37-43** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 and 60-78 of copending Application No. 10/193,721. Although the conflicting claims are not identical, they are not patentably distinct from each other because merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while slightly narrower in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. **Claims 10, 15, 17, 20, 21, 24, 25, 30, 33** and **37-43** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-46 of copending Application No. 10/265,209. Although the conflicting claims are not identical, they are not patentably distinct from each other because merely

reworded representations for the same subject matter, perhaps slightly broader in some aspects while slightly narrower in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. **Claims 10, 15, 17, 20, 21, 24, 25, 30, 33** and **37-43** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-33, 35-37, 43, 44 and 46 of copending Application No. 10/274,497. Although the conflicting claims are not identical, they are not patentably distinct from each other because merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while slightly narrower in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. **Claims 10, 15, 17, 20, 21, 24, 25, 30, 33** and **37-43** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9, 23-25 and 29 of copending Application No. 10/300,655. Although the conflicting claims are not identical, they are not patentably distinct from each other because merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while slightly narrower in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. **Claims 10, 15, 17, 20, 21, 24, 25, 30, 33** and **37-43** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable

over claims 25-44 of copending Application No. 11/145,677. Although the conflicting claims are not identical, they are not patentably distinct from each other because merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while slightly narrower in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

13. **Claims 10, 15, 17, 20, 21, 24, 25, 30, 33** and **37-43** are objected to because of the following informalities. Appropriate correction is required.

a. In **claim 21**, "benigh" should be deleted and —benign— inserted therefor.

b. In **claim 43**, for proper grammatical structure, the phrase "a biodegradable microsphere containers" should deleted and either —at least one biodegradable microsphere container— or —biodegradable microsphere containers—.

Claim Rejections - 35 USC § 101

14. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

15. **Claims 10, 15, 17, 20, 21, 24, 25, 30, 33** and **37-43** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, in **claims 17** and **43**, Applicant recites "***said volume***" and "***said body tissue***." These clauses (and other similar clauses) appear to positively recite a portion of the human body. Although the recitations of "said volume" and "said body tissue" are in inferential clauses, the use of "said" to refer to a body or body part raises the

possibility that Applicant is positively reciting a body part a human being or a human being itself. Accordingly, **claims 17** and **43** are considered to be directed to non-statutory subject matter. 1077 OG 24 (April 21, 1987). Dependent **claims 10, 15, 20, 21, 24, 25, 30, 33** and **37-42** incorporate the non-statutory subject matter recited in the claims from which they depend. Applicant can overcome this rejection by reciting —***the*** volume— and —***the*** body tissue—.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. **Claims 10, 15, 17, 21, 24, 25, 30, 33, 37-39, 41** and **43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (US 5,472,441) in view of Mulier et al. (US 5,807,395).

Regarding **claim 43**, Edwards et al. discloses a method for treating a localized portion of body tissue in a body via inserting a needle apparatus in body tissue, the apparatus including at least one hollow needle core for delivering an electrically conductive substance into the body tissue in the form of a chemotherapeutic fluid, whereby the substance is limited to a localized portion of body tissue (column 7, lines 45-55; column 8, lines 55-65; column 9, lines 22-25; column 10, lines 1-15; column 13; column 16; column 17, lines 1-5; and column 18, lines 5-13). Further, Applicant is

directed to column 16, lines 15-20 where the electrically conductive solution is discussed.

The substance is conveyed in biodegradable microsphere containers, which "are tiny hollow metallic spheres...[with] a thin coating **104** [that] is provided around the entire surface of each of the microspheres **101**" (column 16, lines 35-41). Edwards further discloses, "the coating **104** could simply be biodegradable for chemical stripping by the body's natural fluids...[for] site specific application of the therapeutic drug within the neoplasm...as well as an accurately controlled time release of the drugs into the neoplasm" (column 16, lines 47-52). Applicant has not claimed that the microspheres of the instant application are "entirely" or "completely" biodegradable, and thus, as broadly and reasonably interpreted by the Examiner, the microspheres of the prior art meet the claim limitations of "biodegradable microsphere containers."

In addition, Edwards et al. recites guiding the needle apparatus to a desired volume tissue in need of treatment (column 6, lines 55-65 and column 7, lines 50-55), applying the substance to the volume of tissue through the needle apparatus, determining that the volume of tissue is penetrated by the substance (as discussed throughout the disclosure), and applying RF energy to the substance through an RF electrode to ablate the volume of tissue, where the substance serves an electrode extension conducting the RF energy throughout the volume (as recited throughout the disclosure with emphasis on columns 15-16).

However, Edwards et al. do not explicitly recite a non-invasive imaging technique for guiding the needle However, non-invasive imaging techniques (such as MRI,

ultrasound, etc.) for guiding needles as well as chemotherapeutic fluids in the form of a gel suspension are extremely well known in the art. Specifically, Mulier et al. teaches the use of "ultrasound guidance" of the needle **206** during the medical procedure (column 18, lines 25-43).

Thus, it would be obvious to one with ordinary skill in the art to use a non-invasive imaging technique, such as ultrasound guidance, for the purpose of reducing trauma due to invasive guidance procedures, as taught by Mulier et al.

Regarding **claim 10**, Edwards et al. as modified discloses that as applied to **claim 43** as well as a needle apparatus that includes a biopsy needle guide through which the hollow core needle is inserted and the hollow core needle functions as the RF electrode (columns 13, 15, 16, etc.).

Regarding **claim 15**, Edwards et al. as modified discloses that as applied to **claim 43** as well as the use of imaging contrasting agents (column 17, lines 1-4). Therefore, it is within the scope of the modification to use imaging contrast agents for use in determining the volume of body tissue penetrated.

Regarding **claim 17**, Edwards et al. as modified discloses that as applied to **claim 43** as well as necrosis agents and the use of RF (column 10, lines 55-58 and column 11).

Regarding **claim 21**, Edwards et al. as modified discloses that as applied to **claim 43** as well as a target tissue that is in a prostate and wherein the method is for treating a condition selected from the group of benign prostatic hyperplasia (BPH) and prostate cancer and is accomplished by a method selected from the group of

transrectal, transurethral and transperineal approach (column 6, lines 60-63 and 08/148,441 which is incorporated by reference in column 1, line 11 (a copy has been previously provided)).

Regarding **claim 24**, Edwards et al. as modified discloses that as applied to **claim 43** as well as the method applied for treatment of a body part selected from the group of prostate, liver, uterus, bladder, kidney, lung and breast (column 4, line 14).

Regarding **claim 25**, Edwards et al. as modified discloses that as applied to **claim 24** as well as inserting that is accomplished using an approach selected form the group of percutaneous, laparoscopic and endoscopic (column 6, lines 55-65).

Regarding **claim 30**, Edwards et al. as modified discloses that as applied to **claim 43** as well as guiding that is further performed using a device selected from the group of biopsy apparatus, laparoscope, endoscope, hysteroscope, magnetic resonance imaging (MRI), computed tomography scan (CT scan) and ultrasound imaging apparatus (column 6, lines 55-65).

Regarding **claim 33**, Edwards et al. as modified discloses that as applied to **claim 43** as well as inserting that is performed by at least one method selected from the group of percutaneous, through incision, and through a natural body opening, and a laparoscopic approach, as stated throughout the specification.

Regarding **claim 37**, Edwards et al. as modified discloses that as applied to **claim 43** as well as chemotherapeutic agents such as tissue necrosing agents (column 11). Further, binding agents would be obvious if not inherent.

Regarding **claim 38**, Edwards et al. as modified discloses that as applied to **claim 43** as well as microspheres that have a gas (some air inclusion is inherent). However, the solution of Edwards et al. is comprised of microspheres (column 16). Therefore, it would be obvious and within the scope of the invention to also use microspheres (in a gel suspension) for the conductive solution.

Regarding **claim 39**, Edwards et al. as modified discloses that as applied to **claim 38** as well as a gas that is selected form the group of air, helium, fluorocarbon, and carbon dioxide.

Regarding **claim 41**, Edwards et al. as modified discloses that as applied to **claim 43** as well as a conductive component that is selected from the group consisting of conductive polymers, conductive agents, conductive elements, conductive particles and metallic suspensions (column 16, line 16).

18. **Claims 20, 40** and **42** are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (US 5,472,441) in view of Mulier et al. (US 5,807,395), as applied to **claims 10, 15, 17, 21, 24, 25, 30, 33, 37-39, 41** and **43** above, and further in view of Roskos et al. (US 6,224,883 B1).

Regarding **claim 20**, Edwards et al. as modified discloses that as applied to **claim 43**. Edwards et al. recites the use of microspheres in column 16. However, Edwards et al. do not explicitly recite that the microspheres are contained in a substance for providing image enhancement, such as a gel suspension. On the other hand, Roskos et al. teaches a treatment substance that is in the form of a gel suspension. Therefore, it would be obvious and within the scope of the invention to also

use microspheres in a gel suspension for the conductive solution. Thus, it is within the scope of the invention and obvious to one with ordinary skill in the art to use microspheres (in a gel suspension) for providing image enhancement when the imaging technique is ultrasound (column 16 and column 17, lines 1-5).

Regarding **claim 40**, Edwards et al. as modified discloses that as applied to **claim 37**. However, Edwards et al. do not explicitly recite a treatment substance having a binding agent and that binding agent is selected form the group of biomaterial, polymer, biodegradable polymer, a suspension agent, a derivative of a protein, fat, collagen and oil. On the other hand, Roskos et al. teaches a treatment substance that is in the form of a gel suspension, wherein the gel suspension further has a binding agent and that binding agent is selected form the group of biomaterial, polymer, biodegradable polymer, a suspension agent, a derivative of a protein, fat, collagen and oil, as stated throughout specification. Therefore, it would be obvious to one with ordinary skill in the art at the time the invention was made to modify the invention of Edwards et al. to use a gel suspension for the purpose of increasing viscosity allowing more controlled delivery, as taught by Roskos et al.

Regarding **claim 42**, Edwards et al. as modified disclosed that as applied to **claim 43**. Roskos et al. teaches the use of a chemotherapeutic fluid, such as cisplatin, in the form of "gel formulations for direct injections into a neoplastic lesion or surrounding tissue" (Abstract), which are biodegradable materials fully capable of being contained within the microsphere containers of Edwards et al. (as well as the other way around, i.e. the gel suspension containing microsphere containers). This modification

would necessarily include the conductive gel within a biodegradable container, wherein biodegradable containers are discussed in column 16, lines 47-50 of the prior art specification of Edwards et al.

Conclusion

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese whose telephone number is 571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR
January 27, 2006

Henry Bennett
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Group 3700